



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0115]

Determination of Regulatory Review Period for Purposes of Patent Extension; *Lawsonia Intracellularis* Bacterin Vaccine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has determined the regulatory review period for *Lawsonia Intracellularis* Bacterin Vaccine and is publishing this notice of that determination as required by law. We have made this determination in response to the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that veterinary biologic.

DATES: We will consider all requests for revision of the regulatory review period determination that we receive on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. We will consider all due diligence petitions that we receive on or before [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit revision requests and due diligence petitions by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0115>.
- Postal Mail/Commercial Delivery: Please send your request or petition to Docket No. APHIS-2016-0115, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

A copy of the regulatory review period determination and any revision requests or due diligence petitions that we receive on this determination may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0115> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 851-3426.

For information concerning the regulatory review period determination contact Dr. Patricia L. Foley, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; (515) 337-6100.

#### SUPPLEMENTARY INFORMATION:

The provisions of 35 U.S.C. 156, "Extension of patent term," provide, generally, that a patent for a product may be extended for a period of up to 5 years as long as the patent claims a product that, among other things, was subject to a regulatory review period before its commercial marketing or use. (The term "product" is defined in that section as "a drug product" [which

includes veterinary biological products] or "any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.") A product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

The regulations in 9 CFR part 124, "Patent Term Restoration" (referred to below as the regulations), set forth procedures and requirements for the Animal and Plant Health Inspection Service's (APHIS') review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156. As identified in the regulations, the responsibilities of APHIS include:

- Assisting Patent and Trademark Office of the U.S. Department of Commerce in determining eligibility for patent term restoration;
- Determining the length of a product's regulatory review period;
- If petitioned, reviewing and ruling on due diligence challenges to APHIS' regulatory review period determinations; and
- Conducting hearings to review initial APHIS findings on due diligence challenges.

The regulations are designed to be used in conjunction with regulations issued by the Patent and Trademark Office concerning patent term extension, which may be found at 37 CFR 1.710 through 1.791.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For veterinary biologics, the testing phase begins on the date the authorization to prepare an experimental veterinary biologic became effective and runs until the approval phase begins. The approval phase begins on the date an application for a license was initially submitted for approval and ends on the date such license was issued. Although only a portion of a regulatory review period may count toward the actual amount of extension that the

Commissioner of Patents and Trademarks may award, APHIS' determination of the length of a regulatory review period for a veterinary biologic will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(5)(B).

APHIS recently licensed for production and marketing the veterinary biologic Lawsonia Intracellularis Bacterin Vaccine. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lawsonia Intracellularis Bacterin Vaccine (U.S. Patent No. 5,610,059) from Intervet Inc., a subsidiary of Merck Animal Health, and the Patent and Trademark Office requested APHIS' assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2016, APHIS advised the Patent and Trademark Office that this veterinary biologic had undergone a regulatory review period and that the approval of Lawsonia Intracellularis Bacterin Vaccine represented the first permitted commercial licensing or use of the product. Subsequently, the Patent and Trademark Office requested that APHIS determine the product's regulatory review period.

APHIS has determined that the applicable regulatory review period for Lawsonia Intracellularis Bacterin Vaccine is 1,544 days. Of this time, 186 days occurred during the testing phase of the regulatory review period, and 1,358 days occurred during the approval phase. These periods were derived from the following dates:

1. The date that APHIS started confirmatory testing on the master seed for use in products containing Lawsonia intracellularis: June 20, 2011. APHIS has verified the applicant's claim that the master seed to be used in the Lawsonia Intracellularis Bacterin Vaccine was first put on test by APHIS on June 20, 2011.

2. The date the application for a license was initially submitted for approval under the Virus-Serum-Toxin Act: December 23, 2011. APHIS has verified the applicant's claim that the application was initially submitted on December 23, 2011.

3. The date the license was issued: September 11, 2015. APHIS has verified the applicant's claim that the license for the commercial marketing of the vaccine was issued on September 11, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,544 days of patent term extension.

Section 124.22 of the regulations provides that any interested person may request a revision of the regulatory review period determination within 30 days of the date of this notice (see DATES above). The request must specify the following:

- The identity of the product;
- The identity of the applicant for patent term restoration;
- The docket number of this notice; and
- The basis for the request for revision, including any documentary evidence.

Further, under § 124.30 of the regulations, any interested person may file a petition with APHIS, no later than 180 days after the date of this notice (see DATES above), alleging that a

license applicant did not act with due diligence in seeking APHIS approval of the product during the regulatory review period. The filing, format, and content of a petition must be as described in the regulations in "Subpart D—Due Diligence Petitions" (§§ 124.30 through 124.33).

Authority: 35 U.S.C. 156; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 30<sup>th</sup> day of March 2017.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

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